UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

JUDY ROMERO,	§	
	§	
Plaintiff,	§	Civil Action No. 1:03-CV-01367-MAC
	§	
vs.	§	
	§	
WYETH LLC,	§	Honorable Marcia A. Crone
	§	
Defendant.	§	

WYETH'S REPLY BRIEF IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiff has failed to raise a genuine issue of material fact in response to Wyeth's Motion for Partial Summary Judgment. Therefore, Wyeth is entitled to summary judgment on Plaintiff's failure to warn, design defect, and punitive damages claims.

I. Summary Judgment Is Proper on Plaintiff's Failure-to-Warn Claims.

Plaintiff cannot rebut the presumption in Texas Civil Practice & Remedies Code § 82.007 that Wyeth's FDA-approved warnings were adequate. First, despite Plaintiff's contention that "*Lofton* is easily distinguishable,"[1] the fraud-on-the-FDA exception in (b)(1) is preempted in this case based on the Fifth Circuit's decision in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, No. 10-10956, 2012 WL 579772 (5th Cir. Feb. 22, 2012).[2] Second, there is no evidence that Ms. Romero used hormone therapy ("HT") for an unapproved indication, and therefore the exception in (b)(3) does not apply. Even if Plaintiff could rebut the non-liability presumption in § 82.007, she has presented no reliable expert evidence that Wyeth's warnings

[1] Pl.'s Resp. at 35.

[2] The Fifth Circuit's decision is now final; the plaintiffs did not file a petition for rehearing, and the mandate issued on March 15, 2012. *See* FED. R. APP. P. 40, 41.

were inadequate. Therefore, summary judgment is proper on all of Plaintiff's claims based on an alleged failure to warn.

A. Exception (b)(1) is Preempted.

Lofton held that "§ 82.007(b)(1) is preempted ***unless the FDA itself has found fraud***." 2012 WL 579772, at *8 (emphasis added). Plaintiff, however, claims that (b)(1) is only preempted if the FDA makes an express finding that it was ***not*** defrauded.[3] This, of course, is not what the Fifth Circuit said. It is also inconsistent with the basis for the court's decision. The court concluded that (b)(1) is preempted because it "requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn," and "this requirement invokes federal law supremacy according to *Buckman*." *Lofton*, 2012 WL 579772, at *6. Only a finding of fraud by the FDA itself eliminates the need for the plaintiff to prove fraud on the FDA. Therefore, according to both the text of the opinion and the court's analysis, (b)(1) is preempted unless the FDA itself has found fraud.

It is undisputed that the FDA has not found fraud in this case. Because *Lofton* is binding law in the Fifth Circuit, (b)(1) is preempted, and Plaintiff may not rely on it to rebut the presumption that Wyeth's warnings were adequate.

B. Plaintiff Cannot Satisfy the Requirements for the Exception in (b)(3).

The "over-promotion" exception in (b)(3) similarly does not support Plaintiff's attempt to rebut the presumption that Wyeth's FDA-approved warnings were adequate. Plaintiff launches a barrage of generalized allegations regarding Wyeth's alleged over-promotion of HT. But Plaintiff ignores the fact that the statutory exception she invokes contains ***three*** elements, the last two of which focus directly on the purpose for which the claimant used the product and the cause of the claimant's injury. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(3) (Vernon 2011)

[3] Pl.'s Resp. at 35.

("The claimant may rebut the presumption in Subsection (a) . . . by establishing that . . . (3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the [FDA]; (B) ***the product was used as recommended, promoted, or advertised***; and (C) ***the claimant's injury was causally related to the recommended, promoted, or advertised use of the product*** . . . ." (emphasis added)). In context, it is apparent that the second and third elements of the exception require a showing that the claimant used the product for an indication not approved by the FDA, and that the claimant's injury was causally related to such use. Here, Plaintiff can make neither showing.

First, Ms. Romero did not use HT for an unapproved indication. To the contrary, she admits that she took HT for the relief of menopausal symptoms—the approved indication.[4] Likewise, her doctors did not prescribe HT for an unapproved indication. Dr. Lal explicitly testified that the only reason she prescribed HT to Ms. Romero was to treat her menopausal symptoms—not to treat osteoporosis, not for any cardiovascular benefits, and not to prevent dementia or any other mental illness.[5]

Second, Plaintiff's injury is not causally related to use of HT for an unapproved indication. She did not use HT for an unapproved indication and thus such use could not have contributed to her breast cancer.

Thus, even assuming that there is a genuine issue of fact about the first element of the exception, which requires that the defendant have recommended, promoted, or advertised the product for an unapproved indication, the record shows that Plaintiff cannot establish either the second element or the third element of the exception. For both of these reasons, exception (b)(3)

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4 **Exhibit 22 to Wyeth's Mot. [Dkt. 90-24] –** Oral Deposition of Judy Romero (May 22, 2009) ("Romero Dep.") at 159:13-16, 239:1-5.

5 **Exhibit 24 to Wyeth's Mot. [Dkt. 90-26] –** Oral Deposition of Radha J. Lal, M.D. (Apr. 27, 2011) ("Lal Dep.") at 108:24-109:20.

does not apply and thus does not rebut the presumption that Wyeth's warnings were adequate. Because neither exception (b)(1) nor exception (b)(3) rebuts the presumption that Wyeth's FDA-approved warnings were adequate, Wyeth is entitled to summary judgment on Plaintiff's failure-to-warn claims.

C. Summary Judgment Is Also Proper Because There Is No Reliable Expert Evidence That Wyeth's Warnings Were Inadequate.

There is also an independent ground for granting summary judgment on Plaintiff's failure-to-warn claims: the lack of reliable expert evidence to support those claims. The Response asserts that Plaintiff's experts opine that Wyeth's warnings were inadequate based on the science of the time, but the Response does not present any ***evidence*** that the warnings did not accurately reflect the existing state of scientific knowledge. (It is undisputed that the FDA approved the warnings as an accurate statement of what was known about the risk.) The Response also does not address the previous testimony of Plaintiff's experts that the warnings were "not false" and that "most studies" showed no relation between HT and breast cancer.[6]

Instead, the Response suggests that Plaintiff's experts should be permitted "to testify about the inadequacy of the label based on what Wyeth already knew."[7] But the experts cannot testify about the inadequacy of Wyeth's warnings based on the then-existing state of scientific knowledge for the basic reason that ***the experts did not set forth any such opinion in their expert reports***.

Plaintiff's claim that the warning was inadequate rests on her experts' opinion that Wyeth failed to develop ***additional*** scientific information, i.e., to test as a "reasonable" company purportedly would have done. If this Court grants Wyeth's Motion to Exclude the Testimony of

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6 *See* Wyeth's Mot. at 17-18; Pl.'s Resp. at 35-36.

7 Pl.'s Resp. at 36.

Drs. Parisian, Blume, and Patsner, there will be no evidence to support this allegation, and thus the Court should also grant summary judgment on Plaintiff's failure-to-warn-claims for this additional reason.

II. Plaintiff Has Not Alleged a True Design Defect Claim and Has Not Presented Any Evidence to Support the Elements of a Design Defect Claim.

Plaintiff argues that her design defect claims should survive summary judgment because her "suggested modifications would create safer alternate designs" and "make[] the product even safer."[8] There are no reliable expert opinions to support either of her safer alternative design theories, however. First, there is no reliable scientific evidence that OMP is safer than MPA, and the opinions of Plaintiff's experts should therefore be excluded.[9] Second, Plaintiff has failed to identify any expert opinions supporting her second alternative safer design theory, low-dose HT.[10] Because expert testimony is required to prove both a design defect and a safer alternative design, the absence of expert testimony is fatal to Plaintiff's design defect claims. *See Hunter v. Ford Motor Co.*, 305 S.W.3d 202, 209 (Tex. App.—Waco 2009, no pet.).

Even if Plaintiff's safer alternative design theory of low-dose HT could survive without expert testimony, changing the dosage is not properly viewed as a change in design. And Plaintiff has failed to identify any evidence that a lower dose of HT 1) was feasible at the time she was taking HT; 2) would have worked for her (i.e., her doctor would have prescribed the lower dose and it would have been effective in treating her symptoms); and 3) would have prevented her breast cancer.[11] Each of these gaps in Plaintiff's evidence independently entitles

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8 Pl.'s Resp. at 38.

9 *See* Wyeth's Mot. to Exclude the Testimony of Drs. Austin and Tilley and Brief in Support [Dkt. 85]; Wyeth's Reply in Support of Mot. to Exclude the Testimony of Drs. Austin and Tilley [Dkt. 113].

10 *See* Pl.'s Resp. at 38.

11 *See* Wyeth's Mot. at 21-22.

Wyeth to summary judgment on her design defect claims. Notably, the FDA requires ***all doses*** of Prempro to carry the same labeling with the same warnings about breast cancer. No expert has opined that low-dose Prempro presents a lower risk of breast cancer. To the contrary, Plaintiff's experts have testified in previous trials that they are not aware of any data that low-dose Prempro is safer in terms of breast cancer risk.[12] Without this evidence, Plaintiff cannot prove that low-dose HT would have been a safer alternative design. But in any event, Plaintiff has not pointed to evidence of feasibility or evidence to show that a low-dose medication would have been prescribed for her or would have alleviated her symptoms.

Therefore, even if a lower dose of the same drug could be a safer alternative design generally, there is no evidence, let alone expert testimony, that a lower dose of HT is a safer alternative design in this case. Wyeth is entitled to summary judgment on Plaintiff's design defect claims.

III. There Is No Evidence to Support Plaintiff's Claim for Punitive Damages.

Plaintiff has identified no evidence in this case, much less clear and convincing evidence, that her breast cancer resulted from fraud, malice, or gross negligence. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 41.003(a) (Vernon 2011). Instead of specifically identifying the evidence in ***this case*** that Plaintiff contends shows that Wyeth acted with the requisite intent for fraud, malice, or gross negligence under Texas law, Plaintiff merely says that there is a genuine issue of material fact in this case because this Court found a genuine issue of material fact in *Lea*.[13] This assertion is insufficient to create a fact issue on her claim for punitive damages, because the non-movant must "identify specific evidence in the record and articulate the 'precise manner' in

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[12] *See, e.g.*, Testimony of Dr. Donald F. Austin, Feb. 6, 2008 Trial Transcript, *Scroggin v. Wyeth*, MDL Docket No. 4:03-cv-1507-wrw, at 324-25 (E.D. Ark.) (stating that he had not seen any studies addressing the effect of dose on breast cancer risk).

[13] Pl.'s Resp. at 40.

which that evidence support[s] [its] claims." *Forsyth v. Barr*, 19 F.3d 1527, 1537 (5th Cir. 1994). The non-movant's burden is even greater where, as is true as to the issue of punitive damages in this case, the non-movant bears the burden of proof and the standard of proof is clear and convincing evidence. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). Because Plaintiff has not carried her burden, Wyeth is entitled to summary judgment on Plaintiff's claim for punitive damages.

IV. Conclusion

Plaintiff has not pointed to evidence creating any genuine issues of material fact. Therefore, Wyeth asks this Court to enter summary judgment in its favor on Plaintiff's failure to warn, design defect, and punitive damages claims, and grant Wyeth all other relief to which it may be entitled.

Dated: March 26, 2012

Respectfully Submitted,

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ATTORNEYS FOR DEFENDANT

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of March, 2012 a true and correct copy of the foregoing was filed with the Court and served via electronic notification on all counsel of record.

/s/ John H. Martin
John H. Martin

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